



7020-02

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1032]

Certain Single-Molecule Nucleic Acid Sequencing Systems and Reagents, Consumables, and Software for Use with Same

Commission's Final Determination Finding No Violation of Section 337; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has found no violation of section 337 of the Tariff Act of 1930, as amended, in this investigation. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Lucy Grace D. Noyola, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW, Washington, DC 20436, telephone 202-205-3438. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW, Washington, DC 20436, telephone 202-205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (<https://www.usitc.gov>). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on December 8, 2016, based on a complaint filed by Pacific Biosciences of California, Inc. of Menlo Park, California (“PacBio”). 81 FR 88703, 88703-04 (Dec. 8, 2016). The complaint, as amended, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain single-molecule nucleic acid sequencing systems and reagents, consumables, and software for use with same by reason of infringement of certain claims of U.S. Patent Nos. 9,404,146 (“the ’146 patent”) and 9,542,527 (“the ’527 patent”). *Id.* at 88704; 82 FR 15236 (Mar. 27, 2017). The notice of investigation named as respondents Oxford Nanopore Technologies Ltd. of Oxford, United Kingdom; Oxford Nanopore Technologies, Inc. of Cambridge, Massachusetts; and Metrichor, Ltd. of Oxford, United Kingdom (collectively, “Oxford”). 81 FR at 88704. The Office of Unfair Import Investigations (“OUII”) also was named as a party to the investigation. *Id.*

On May 23, 2017, the presiding administrative law judge (“ALJ”) issued Order No. 10 (“*Markman* Order”), construing the limitations “single-molecule sequencing process,” which is recited in claims 1, 5-7, 14, and 16-17 of the ’146 patent and claims 1 and 3-4 of the ’527 patent, and “single-molecule sequencing,” which is recited in claims 20-21 of the ’146 patent (collectively, “single-molecule sequencing” limitations).

On June 8, 2017, PacBio filed a motion for summary determination that the domestic industry requirement is satisfied. On June 9, 2017, Oxford filed a motion for summary determination of (1) noninfringement as to all accused products because they do not satisfy the “single-molecule sequencing” limitations; (2) noninfringement as to a subset of the accused products (directed solely to Oxford’s 1D or 1D² sequencing processes) because they do not satisfy the “linker”

limitations; and (3) noninfringement as to a subset of the accused products (not directed solely to Oxford's 1D or 1D² sequencing processes) because they are capable of substantial noninfringing uses.

On July 19, 2017, the ALJ issued an ID (Order No. 12), granting in part Oxford's summary determination motion. Specifically, the ID incorporated the *Markman* Order by reference and found no infringement of claims 1, 5-7, 10, 14, 16-21, and 23-25 of the '146 patent and claims 1 and 3-11 of the '527 patent based on the *Markman* Order's construction of the "single-molecule sequencing" limitations. The ID denied as moot Oxford's second and third requests for summary determination of noninfringement, as well as PacBio's motion for summary determination on the economic prong of the domestic industry requirement. The ID found no violation of section 337.

On July 31, 2017, PacBio filed a petition for review of the *Markman* Order's construction of "single-molecule sequencing" and the ID's finding of noninfringement. On August 7, 2017, Oxford and OUII filed responses to PacBio's petition. On August 16, 2017, PacBio filed a motion for leave to file a reply in support of its petition for review. On August 28, 2017, Oxford filed an opposition to PacBio's motion.

On September 5, 2017, the Commission determined to review the ID in its entirety and to deny PacBio's motion for leave to file a reply. Notice (Sept. 5, 2017). The Commission also requested additional briefing from the parties on certain issues.

On September 15, 2017, Oxford and OUII filed initial written submissions addressing the Commission's questions. On September 18, 2017, PacBio filed its initial written submission. On September 22, 2017, Oxford and OUII filed response briefs. On September 22, 2017, and September 29, 2017, PacBio filed its response briefs.

Having examined the record of this investigation, including the ID and the parties' submissions, the Commission has determined to adopt, on modified grounds described in the concurrently-issued opinion, the *Markman* Order's construction of the "single-molecule sequencing" limitations. The Commission has also determined to affirm the ID's finding of noninfringement of claims 1, 5-7, 10, 14, 16-21, and 23-25 of the '146 patent and asserted claims 1 and 3-11 of the '527 patent and the ID's finding of no violation of section 337. The Commission denies PacBio's request for oral argument.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 C.F.R. part 210).

By order of the Commission.

Issued: February 7, 2018.

Lisa R. Barton,
Secretary to the Commission.

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